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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,564	12/12/2003	Jon H. Astle	1657/2012	2507

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EXAMINER

GODDARD, LAURA B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/734,564	Applicant(s) ASTLE ET AL.	
	Examiner Laura B. Goddard, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to a method of diagnosing colon cancer comprising detecting the presence of **TIMP1 protein** and at least one other colon cancer-specific protein marker, classified in class 435, subclass 7.1.
- II. Claims 12-14, drawn to a method of diagnosing colon cancer comprising detecting the presence of **nucleic acid that encodes TIMP1** and at least one other nucleic acid molecule which encodes at least one other colon cancer-specific marker, classified in class 435, subclass 6.
- III. Claims 15-25, drawn to a method of diagnosing colon cancer comprising detecting the presence of **Reg1 $\alpha$  protein** and at least one other colon cancer-specific protein marker, classified in class 435, subclass 7.1.
- IV. Claims 26-28, drawn to a method of diagnosing colon cancer comprising detecting the presence of a **nucleic acid molecule which encodes Reg1 $\alpha$  protein** and at least one other nucleic acid molecule which encodes at least one other colon cancer-specific marker, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-IV are materially distinct methods which differ at least in method steps and reagents. For example, the Groups are drawn to a method of diagnosing colon cancer, however, each of the groups employs chemically distinct reagents to accomplish the different method steps for detecting structurally and functionally different molecules. Searching all of the groups with the different method steps and reagents would invoke a high burden of search.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

## **SPECIES ELECTION**

### **Species election for Group I**

This application contains claims directed to the following patentably distinct, structurally and functionally different **colon cancer specific marker** species of the claimed invention: the nucleic acid molecules of SEQ ID NOs: 1, 3, 5-71, the polypeptide molecules of SEQ ID NOs: 2, 4, 72-138, CA 19-9, CA 72-4, TF, sTN, Tn, CA 50, CA 549, CA 242, LASA, or Du-PAN 1-5 (claim 7).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 6 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

### **Species election for Group II**

This application contains claims directed to the following patentably distinct, structurally and functionally different **colon cancer specific marker** species of the claimed invention: the nucleic acid molecules of SEQ ID NOs: 1, 3, 5-71, the polypeptide molecules of SEQ ID NOs: 2, 4, 72-138, CA 19-9, CA 72-4, TF, sTN, Tn, CA 50, CA 549, CA 242, LASA, or Du-PAN 1-5 (claim 14).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 13 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

### **Species election for Group III**

This application contains claims directed to the following patentably distinct, structurally and functionally different **colon cancer specific marker** species of the claimed invention: the nucleic acid molecules of SEQ ID NOs: 1, 3, 5-71, the polypeptide molecules of SEQ ID NOs: 2, 4, 72-138, CA 19-9, CA 72-4, TF, sTN, Tn, CA 50, CA 549, CA 242, LASA, or Du-PAN 1-5 (claim 21).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 20 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

### **Species election for Group IV**

This application contains claims directed to the following patentably distinct, structurally and functionally different **colon cancer specific marker** species of the claimed invention: the nucleic acid molecules of SEQ ID NOs: 1, 3, 5-71, the polypeptide molecules of SEQ ID NOs: 2, 4, 72-138, CA 19-9, CA 72-4, TF, sTN, Tn, CA 50, CA 549, CA 242, LASA, or Du-PAN 1-5 (claim 28).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 27 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.  
Examiner  
Art Unit 1642

  
JEFFREY SIEW  
SUPERVISORY PATENT EXAMINER  
11/22/05